

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-834/S007

Trade Name: Plendil

Generic Name: Felodipine

Sponsor: Astra Merck

Approval Date: July 29, 1999

Indications: The treatment of hypertension.

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RESEARCH**

APPLICATION NUMBER:
19-834/S007

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Reviews / Information Included in this NDA Review.

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Medical Review(s)	
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Statistical Review(s)	
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Clinical Pharmacology/ Biopharmaceutics Review(s)	
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APPLICATION NUMBER:

19-834/S007

APPROVAL LETTER

JUL 29 1996

NDA 19-834/S-007

Astra Merck
Attention: Daniel J. Cushing, Ph.D.
725 Chesterbrook Blvd.
Wayne, PA 19087-5877

Dear Dr. Cushing:

Please refer to your May 10, 1996 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PLENDIL (felodipine) Extended-Release 2.5 mg, 5 mg and 10 mg Tablets.

The supplemental application provides for the current manufacturing description in greater detail and to account for changes _____

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

Sincerely yours,

BJW 7/29/96

Robert J. Wolters, Ph.D.
Chemistry Team Leader, DNDC-1
Division of Cardio-Renal Drug Products (HFD-110)
Office of Drug Evaluation 1
Center for Drug Evaluation and Research

cc:

Original NDA

HFR-MA 140/Karen Campbell

HFD-110

HFD-110/Project Manager

HFD-80

HFD-810/CHOiberg

HFD-110/RMittal/6/28/96

kc/6/28/96; 7/26/96

Approval Date: July 25, 1991.

APPROVAL

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RESEARCH**

APPLICATION NUMBER:

19-834/S007

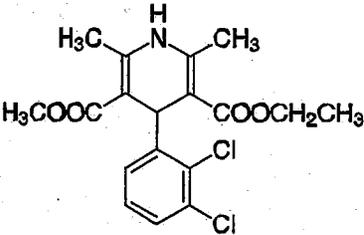
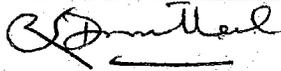
CHEMISTRY REVIEW(S)

JUL 26 1996

NDA 19-834

PLENDIL

ASTRA-MERCK

CHEMIST'S REVIEW		1. ORGANIZATION HFD - 110	2. NDA Number 19-834
3. Name and Address of Applicant (City & State) Astra Merck 725 Chesterbrook Blvd. Wayne, Pa 19087-5677		4. Supplement(s) Number/Date SCS-007 05-10-96	
5. Drug Name PLENDIL	6. Nonproprietary Name Felodipine		8. Amendments & Other (reports, etc) - Dates
7. Supplement provides for: the current manufacturing description in great detail, and to account for changes _____ _____ _____			
9. Pharmacological Category Hypertension		10. How Dispensed <input checked="" type="checkbox"/> / RX <input type="checkbox"/> / OTC	11. Related IND(s)/ NDA(s)/DMF(s)
12. Dosage Form(s) Tablets		13. Potency(ies) 2.5 mg, 5 mg, and 10 mg	
14. Chemical Name and Structure (±) Ethylmethyl 4-(2,3-dichlorophenyl)-1,4-dihydro-2,6-dimethyl-3,5-pyridine-dicarboxylate. 			15. Records/Reports Current <input checked="" type="checkbox"/> / Yes <input type="checkbox"/> / No Reviewed <input checked="" type="checkbox"/> / Yes <input type="checkbox"/> / No
16. Comments: See review on following pages.			
17. Conclusions and Recommendations: Satisfactory and approval letter is being sent.			
18. REVIEWER			
Name Ramsharan D. Mittal	Signature 		Date Completed 07-25-96
19. Distribution: <input type="checkbox"/> / Original Jacket <input type="checkbox"/> / Reviewer <input type="checkbox"/> / Division File <input type="checkbox"/> / CSO			

Karen Campbell HFR-MA140

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5 Page(s) Withheld

§ 552(b)(4) Trade Secret / Confidential

§ 552(b)(5) Deliberative Process

§ 552(b)(4) Draft Labeling